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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,653	12/01/2000	Wei Han	PH-7118	5964

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EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/18/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/728,653

Applicant(s)

HAN, WEI

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 12, 16, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 and 16 is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 12 is/are rejected.
- 7) ☐ Claim(s) 3, 4, 7 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Pursuant to the directives of paper No. 12 (filed 5/19/03), claims 1, 3-5, 12, 16 have been amended, claims 8-11, 13-15, 17-20 cancelled, and claims 21-22 added. Claims 1-7, 12, 16, 21, 22 are pending.

Claims 1-7, 12, 16 are examined in part; claims 21-22 are withdrawn from consideration. Applicants' arguments filed 5/19/03 have been considered and found persuasive. The previously imposed rejections are withdrawn. Claims 5 and 16 are characterized as allowable; claims 3, 4, 7, 16 are objected to because of their dependence on rejected claims.

※

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Sohda (WO 96/16079)

Sohda discloses (page 63) the compound of example 17. This is encompassed by claim

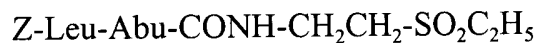
1 when the substituent variables correspond as follows:

R9 = (Me)₂-CH-CO-
A2 = a bond
A3 = a bond
A4 = a bond
A5 = a bond
A6 = the amino acid valine
R1 = benzyl
R2 = hydrogen
W = -NH-
Q = a C₁-alkyl group that is substituted with phenyl (i.e., benzyl)

*

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Harbeson (USP 5,541,290).

Harbeson discloses (table 1, col 25) the following compound:



This anticipates claim 1 for the following case:

R9 = carboxybenzyloxy
A2 = a bond
A3 = a bond
A4 = a bond
A5 = a bond
A6 = the amino acid leucine
R1 = alkyl
R2 = hydrogen
W = -NH-
Q = a C₂-alkyl group that is substituted with Q1
Q¹ = SO₂-R₁₁

R¹¹ = ethyl

Thus, the claims are anticipated.

*

Claim 1 is rejected under 35 U.S.C. §102(e) as being anticipated by Bailey (USP 6,291,640).

Bailey discloses various compounds in column 15. The first of these is encompassed by instant claim 1 when the substituent variables correspond as follows:

R9 = (Me)₃-CCH₂-CO-
A2 = a bond
A3 = a bond
A4 = a bond
A5 = an amino acid
A6 = an amino acid
R1 = methyl
R2 = hydrogen
W = -NH-
Q = a C₂-alkyl group that is substituted with naphthyl

Thus, the claim is anticipated.

*

Claims 1-2 are rejected under 35 U.S.C. §102(b) as being anticipated by Takeuchi (USP 5162500)

Takeuchi discloses (col 2, line 25+) compounds of formula I; examples of the compounds are recited in table 2 (col 31, line 1+). Compound #5 is encompassed by instant claim

1 when the substituent variables correspond as follows:

R9 = tBoc
A2 = a bond
A3 = a bond
A4 = a bond
A5 = a bond
A6 = an amino acid
R1 = ethyl
R2 = hydrogen
W = -NH-
Q = an amino acid (i.e., leucine *tert*-butyl ester)

An alternative to the foregoing is that variable "Q" is $((CR^{10})(R^{10c}))\text{-}Q^1$, wherein R^{10} is C_4 -alkyl, R^{10c} is hydrogen, and Q^1 is $\text{-CO}_2\text{-C}_4\text{H}_9$

Thus, the claims are anticipated.

✱

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each

claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 12 is rejected under 35 U.S.C. §103 as being unpatentable over Sohda (WO 96/16079) or Harbeson (USP 5,541,290) or Bailey (USP 6,291,640) or Takeuchi (USP 5162500).

The teachings of the references are indicated above. None of the references "singles out" the compounds cited by the examiner for combining with a pharmaceutically acceptable carrier. However, each of the references discloses pharmacological activity, and so it would have been obvious to a drug formulation specialist of ordinary skill to combine each of the compounds with a pharmaceutically acceptable carrier.

Thus, the claim is rendered obvious.

*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800